REMARKS

Claims 26-41 are pending in the present application. Claims 26 and 34 have been amended. Claim 33 has been cancelled and new Claims 42-44 have been added.

Support for amended Claim 34 and new Claims 42-44 can be found in the claims as originally filed and in the specification at, for example, paragraphs **[0016]**, **[0041]**, **[0052]**, and **[0055]**. Claim 26 has been amended to correct a minor typographical error. Accordingly, no new matter has been added to the application by entering this amendment.

In view of the remarks set forth below, Applicants respectfully submit that the application is now in condition for allowance.

Rejections Under 35 U.S.C. § 102

The Examiner has rejected Claims 26-41 under 35 U.S.C. § 102(b), as allegedly being anticipated by Hellstrand *et al.*, WO 97/42968 (WO '968). Specifically, the Examiner asserts that WO '968 teaches methods for obtaining and using histamine-inducing compounds for the preparation of a medicament to be applied through transdermal formulations. The Examiner further asserts that WO '968 teaches a wide variety of routes of administration and carriers for the composition, including powders, dispersions, glycerol, polyethylene glycol, mixtures and oils. Thus, the Examiner concludes that it is "conceivable that such variety of formulations and carriers can be made into cosmetic powders, moisturizers, etc. through mere additive or subtractive effects to achieve a desired formulation."

The Examiner has also rejected Claims 26, 27, 29, 34, and 36 under 35 U.S.C. § 102(b), as allegedly being anticipated by Bruce *et al.*, WO 95/23601 (WO '601). Specifically, the Examiner asserts that WO '601 teaches that histamine phosphate in its precursor form (pro-drug) can be used for the preparation of the active drug for use in a composition. The Examiner concludes that because WO'601 discloses that the preparation is effective for skin damage such as blisters or cold sores, the formulation can be used as a lipstick or other lip preparations such as gels.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and

limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) (emphasis added).

Applicant respectfully submits that neither reference anticipates the claims of the instant application. Independent Claims 26 and 34 recite, in relevant part, "a cosmetic composition." Thus, the claimed invention relates to cosmetic compositions, and the use of such cosmetic compositions, wherein the claimed compositions comprise an effective dose of a histamine or histamine-related compound that inhibits the production and release of ROMs in a cosmetically acceptable carrier adapted for topical delivery as a cosmetic product. Thus, in some embodiments, the compositions include adornments such as color, fragrance, and texture.

WO '968 discloses pharmaceutical compositions comprising a compound selected from the group consisting of histamine, histamine dihydrochloride, histamine phosphate, histamine salts, histamine esters, H_2 receptor agonists, 5HT antagonists, serotonin, retinoic acid, retinoids, IL-3, ingestible allergens and a pharmaceutically acceptable carrier such as water, ethanol, polyols, liquid polyethylene glycols and oils. The compositions and methods of treating malignancies or infectious diseases disclosed in WO '968 all involve the systemic administration of histamine and a second beneficial agent to achieve stable levels of circulating histamine in the blood. Such systemic, stable histamine levels, according to WO '968, are efficacious in combating cancer or other infectious diseases.

WO '601 describes a method and composition for topical treatment of damaged tissue using histamine phosphate as the active ingredient. The damaged tissue includes the diseases of herpes labialis, aphthous stomatitis, lesions, herpes genitalis, chicken pox, allergic conjunctivitis, giant papillary conjunctivitis, stomatitis secondary to chemotherapy, oral mucositis secondary to chemotherapy, thermal burn, sunburn, decubitus ulcers, and shingles.

Neither of the cited references discloses a cosmetic composition comprising an effective dose of a histamine or histamine-related compound that inhibits the production and release of ROMs in a cosmetically acceptable carrier adapted for topical delivery as a cosmetic product. Rather, WO '968 and WO '601 disclose only therapeutic compositions. Such traditional therapeutic compositions focus on remedial agents that simply treat the disease while neglecting a patient's aesthetic concerns. These traditional therapeutic compositions would not consider

ingredients such as color, fragrance, and texture, or any other aesthetic features. This difference between a traditional therapeutic composition and a cosmetic composition is substantial from a patient's perspective when considering the aesthetics of disease treatment. While WO '968 discloses pharmaceutically acceptable carriers, such as polymers, gels, microspheres, and liposomes, and WO '601 discloses a water soluble vinyl polymer gel base, neither reference considers a carrier that is a cosmetic product. Likewise, neither reference considers the color, fragrance, and texture qualities of the cosmetic composition of some embodiments of the claimed invention. Because anticipation requires that there be no difference between the claimed invention and the reference disclosures, Applicant respectfully submits that the cited references do not anticipate the claimed invention.

Furthermore, WO '968 speaks to the systemic administration of histamine in order to establish stable levels of histamine in the blood. In contrast, the cosmetic carriers claimed in the instant application focus on the topical administration of compounds effective to treat and/or prevent ROM-mediated oxidative damage to a subject's skin or mucosa. The claims of the instant application recite topical delivery of the claimed compounds. Because topical delivery of the compounds is a meaningful feature of the claims, it must be considered in evaluating the patentability of the claims. WO '968 does not disclose the non-systemic administration of histamine and histamine-related compounds for the treatment and/or prevention of disorders of the skin or mucosa. Thus, WO '968 does not teach every limitation of the claimed invention.

Because neither WO '968 nor WO'601 teaches every limitation of the claimed invention, Claims 26-41 are novel under 35 U.S.C. § 102(b). Accordingly, Applicant respectfully requests withdrawal of all rejections under this section and allowance of the pending application.

Rejection Under 35 U.S.C. § 103

The Examiner rejected Claims 28, 29, 30, 34-41 under 35 U.S.C. § 103(a) as being unpatentable over Bruce et al. (WO '601) in view of Bathurst et al., U.S. Patent No. 6,004,579 (the '579 patent).

To establish a *prima facie* case of obviousness, three basic criteria must be met: first, there must be a suggestion or motivation to modify the reference to achieve the claimed invention; second, there must be a reasonable expectation of success derived from the cited

reference in practicing the claimed invention; and third, the cited references must teache or suggest all the limitations of the claimed invention. M.P.E.P. § 2143. Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness in the Office Action mailed January 14, 2004, and that the present rejection should be withdrawn.

The first criterion in establishing a *prima facie* case of obviousness is that there must be a suggestion or motivation to modify the reference or to combine reference teachings to achieve the claimed invention. "[I]t is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016 (CCPA 1972); M.P.E.P. § 2143.01. A comparison of the pending claims with the subject matter disclosed in the cited references shows that these references do not provide the necessary teachings to practice the claimed invention. Therefore, the cited references are insufficient to support an obviousness rejection.

The claims of the instant application relate to cosmetic compositions, and the use of such cosmetic compositions, wherein the compositions comprise an effective dose of a histamine or a histamine-related compound that inhibits the production and release of ROMs in a cosmetically acceptable carrier adapted for topical delivery as a cosmetic product. Thus, in some embodiments, the compositions include adornments such as color, fragrance, and texture.

Unlike traditional therapeutic agents that simply treat a disease, cosmetic compositions focus on the treatment of the disease while simultaneously addressing the patient's aesthetic concerns. Accordingly, cosmetic compositions include ingredients such as color, fragrance, and texture, or any other aesthetic features. This difference between a traditional therapeutic composition and a cosmetic composition is substantial from a patient's perspective when considering the aesthetics of disease treatment.

WO '601 is applied as in the rejection under 35 U.S.C. § 102 above. The compositions disclosed in WO '601 are described throughout the disclosure as providing "an effective remedy," or "an improved medication and treatment," or the like. The reference lacks any teaching or suggestion of a compound that goes beyond treatment of the disease and addresses a patient's cosmetic concerns. In fact, the Examiner notes that WO '601 does not teach that the histamine phosphate composition can be made as a lipstick, shampoo, spray, or mouthwash formulation. Prior to the claimed invention, the use of cosmetic compositions comprising a

histamine or a histamine-related compound in a cosmetically acceptable carrier was not contemplated. The benefits of formulating the claimed compositions to take into account a patient's aesthetic concerns were unrecognized. WO '601 did not contemplate a patient's aesthetic concerns, and thus provides no teaching or suggestion to provide the histamine phosphate compositions in a cosmetically acceptable carrier.

Nevertheless, the Examiner asserts that claimed invention is obvious in view of the '579 patent, which teaches that the phospholipid-containing compositions disclosed therein can be formulated into various topically acceptable liquids, creams, lotions, gels, etc. The Examiner concludes that one of ordinary skill in the art would have been motivated to make a composition for topical treatment of skin conditions mediated through ROM in many formulations (e.g., shampoo, lotions, lipstick, or spray) and that one of ordinary skill in the art would have expected to obtain an effective topical treatment of skin damage without being limited to only one formulation, thereby increasing market acceptability. However, there is nothing contained in the '579 patent to support the assumption that the phospholipid-containing composition formulations taught by the '579 patent would be useful in formulating compositions other than the disclosed phospholipid-containing compositions. Furthermore, there is no teaching or suggestion to use the disclosed formulations with compositions other than phospholipid-containing compositions. Thus, neither reference provides the necessary suggestion or motivation to combine the references.

The second criterion of obviousness is that there must be a reasonable expectation of success derived from the cited reference in practicing the claimed invention. *In re Merck & Co., Inc.,* 800 F.2d 1091 (Fed. Cir 1986); M.P.E.P. § 2143.02. At least some degree of predictability is required with respect to a reasonable expectation of success. Neither reference teaches the claims of the instant application nor does either reference provide one of skill in the art with a reasonable expectation of success in practicing the claimed invention. In fact, WO '601 is completely silent as to the benefits of administering compounds in a cosmetically acceptable carrier. Therefore, WO '601 does not provide sufficient teachings to render the claimed invention obvious. Furthermore, there is no discussion in the '579 patent concerning providing compositions other than phospholipid compositions in a cosmetic carrier. In the absence of such teachings, one of skill in the art would have no reasonable expectation of success in practicing the claimed invention based on the disclosure of the cited references. Given the lack of a

reasonable expectation of success when practicing the claimed invention in view of the cited art, the second criterion for establishing a *prima facie* case of obviousness has not been met.

The third criterion is that the cited art must teach or suggest all the limitations of the claims. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); M.P.E.P. § 2143.03. The claims of the instant application relate to a compound selected from the group consisting of histamine, histamine dihydrochloride, histamine diphosphate, other histamine salts, esters, prodrugs, histamine-receptor agonists, serotonin, and 5HT agonists and a cosmetically acceptable carrier. As discussed above, WO '601 does not teach or suggest providing the histamine phosphate compositions in a cosmetically acceptable carrier or the use of compounds other than histamine phosphate. In addition, the '579 patent does not disclose the use of compounds other than the phospholipid-containing compounds. Because the cited art does not teach or suggest all limitations of the claims, this criterion of obviousness has not been established.

In light of the foregoing, Applicant respectfully submits that Claims 28, 29, 30, 34-41 are not obvious under 35 U.S.C. 103 in view of WO '601 and the '579 patent. Accordingly, Applicant hereby requests that this rejection be withdrawn.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the application is now in condition for allowance. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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